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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,079	10/27/2000	Donna K. Fox	0942.4460002/RWE/BJD	7547

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/10/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/697,079	FOX ET AL.
Examiner	Art Unit	
Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 October 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 45,49 and 52-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 45,49 and 52-58 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u> .	6) <input type="checkbox"/> Other: _____.

FINAL ACTION

1. This action is in response to paper no. 15, filed October 29, 2002. Claims 46-48 have been canceled, claim 45 has been amended, and claims 53-58 have been added. Claims 45, 49, and 52-58 are now pending. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANTS AMENDMENTS TO THE CLAIMS:**

4. Claims 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57-58 are indefinite over the recitation of the limitation "wherein said one or more restriction endonucleases and said one or more polymerase inhibitors are present in said composition at working concentrations or at concentrations greater than working concentrations." The specification teaches that the term "working concentration" means "the concentration of a reagent that is at or near the optimal

concentration used in a solution to perform a particular function." However, the instant claims are not, e.g., drawn to a particular method, or otherwise limited to any type of function; rather, the claims are drawn to compositions comprising particular reagents. Thus, it is unclear as to how or whether the requirement for a reagent to be present at "working concentration" or a concentration greater than "working concentration" limits the claims. Clarification is required.

Claim Rejections - 35 USC § 102

5. In view of the cancellation of claims 46-48, the rejection of these claims under 35 U.S.C. 102(a) as being clearly anticipated by Todd (WO 96/32500 [10/1996]) is moot.
6. In view of the amendment of claim 45 to require a composition that "does not contain any nucleic acid molecules," the rejection of claims 45, 49 and 52 under 35 U.S.C. 102(a) as being clearly anticipated by Todd is withdrawn.
7. In view of the cancellation of claims 46-48, the rejection of these claims under 35 U.S.C. 102(b) as being clearly anticipated by the GibcoBRL Life Technologies Catalogue and Reference Guide (page 6-29, 1993-1994) is moot.
8. In view of the amendment of claim 45 such that the claim is limited to the particular types of polymerase inhibitors recited therein, the rejection of claims 45-46, 49 and 52 under 35 U.S.C. 102(b) as being clearly anticipated by the GibcoBRL Life Technologies Catalogue and Reference Guide is withdrawn.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANTS AMENDMENTS TO THE CLAIMS:**

11. Claims 45, 49, and 52-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd (WO 96/32500 [10/1996]) in view of Sobol et al (U.S. Patent No. 5,543,296 [8/1996]) and Isner (U.S. Patent No. 5,652,225 [7/1997; effective filing date 10/1994]).

Todd discloses the preparation of compositions for nucleic acid amplification by PCR (see, e.g., page 22). Todd discloses several reagents that are combined during preparation of the PCR reaction mixture, including a restriction endonuclease, anti-Taq polymerase antibodies, and multiple buffers (see entire reference, especially p. 19, lines 11-21; page 22, lines 8-21). However, the instant claims require a composition that "does not contain any nucleic acid molecules" (see independent claims 45 and 53). As

Todd does not disclose the order in which the reagents of the PCR reaction mixture are combined with one another, Todd does not disclose a composition meeting the requirements of the claims. Sobol et al disclose the use of master mixes of reagents while preparing multiple samples for PCR (col 17, lines 19-44; col 18, lines 25-50). It is well known to those of skill in the art that a master mix is typically employed when performing multiple PCR reactions, in order to improve efficiency. Further, Isner et al disclose that the use of master mixes in the preparation of enzymatic reaction mixtures results in "greater accuracy and reproducibility" (see column 15, lines 37-39). Sobol et al disclose the preparation of a PCR master mix that includes all PCR reagents (including polymerase) other than primers and template (see col 17, lines 19-44; col 18, lines 25-50). In view of the teachings of Sobol et al and Isner, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have prepared the PCR reaction mixtures of Todd by first preparing a master mix composition including all reagents other than template and primers, which master mix composition would meet the requirements of the instant claims. An ordinary artisan would have been motivated to have made such a modification for the advantage of efficiency, accuracy, and reproducibility in conducting PCR amplification. Further, an ordinary artisan would have been motivated to have prepared a master mix including all reagents but template and primers in order to have possessed a single master mix composition that could be employed successfully with a variety of templates and primers, as exemplified by Sobol et al, for the advantages of convenience and efficiency.

Regarding claim 45 and claims dependent therefrom, it is noted that it is a property of the anti-*Taq* polymerase antibodies disclosed by Todd that they constitute binding proteins. With respect to claim 49, it is noted that the claim is sufficiently broad so as to encompass storage under any type of conditions for any length of time, and it is an inherent property of the master mix suggested by Todd in view of Sobol et al and Isner that it would be "stable upon storage" under appropriate conditions (e.g., in a freezer). Regarding claims 57-58, it is noted that it is a property of the master mix suggested by Todd et al in view of Sobol et al and Isner that they enzymes contained therein are present "at working concentrations or at concentrations greater than working concentrations."

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
January 10, 2003



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600